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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,395	02/25/2002	Frank Diehl	22012.PUS	4534

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,395

Applicant(s)

DIEHL ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 4-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Objections

1. Claims 4-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-11 not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11 are indefinite in Claim 1 for the recitation "the obtained solution" because the recitation lacks proper antecedent basis in the claim. It is suggested that Claim 1 be amended to provide proper antecedent basis e.g. in line 3, after "betaines" insert, "to obtain a solution of nucleic acids".

Claims 1-11 are indefinite in Claim 1 for the recitations "being applied to a carrier" and "being bound to the carrier" because it is unclear whether the recitations are method steps of applying and binding or whether the recitations refer to a future use for the solution and nucleic acids. It is suggested that Claim 1 be amended to recite positive and active method steps e.g. applying and binding.

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Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

Claim 12 provides for the use of betaines but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cronin et al (U.S. Patent No. 6,045,996, issued 4 April 2000).

Regarding Claim 1, Cronin et al disclose a process for binding nucleic acids to a carrier wherein the nucleic acids are dissolved in a solvent containing at least one betaine, applying

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the nucleic acid-betaine solution to the carrier whereby the nucleic acids are bound to the carrier i.e. via hybridization to probe immobilized on the carrier (Column 10, line 48-Column 11, line 20).

Regarding Claim 2, Cronin et al disclose the process wherein the betaine is trimethylammonium acetate (Column 4, lines 22-31).

Regarding Claim 3, Cronin et al disclose the process wherein the betaine is present at a concentration of 8mM to 6.5M (Column 4, lines 3-31 and Column 5, lines 11-12).

Regarding Claim 5, Cronin et al disclose the process wherein the carrier is made of glass (Column 10, lines 17-19).

Regarding Claim 12, Cronin et al disclose the use of betaines as additives for solvents in which nucleic acids are dissolved in order to bind them to a carrier i.e. via hybridization to probe immobilized on the carrier (Column 10, line 48-Column 11, line 20).

6. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Ness et al (U.S. Patent No. 6,027,890, issued 22 February 2000).

Regarding Claim 12, Ness et al disclose the use of betaines as additives for solvents in which nucleic acids are dissolved in order to bind them to a carrier i.e. Ness et al dissolves nucleic acids in triethylammonium acetate to separate the fragments via high performance liquid chromatography in order to bind the separated fragments on to a carrier (Column 56, lines 3-33).

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ness et al (U.S. Patent No. 6,027,890, issued 22 February 2000).

Regarding Claim 1, Ness et al teach a method for binding nucleic acids to a carrier wherein the nucleic acids are dissolved in a solvent containing at least one betaine i.e. Ness et al dissolves nucleic acids in triethylammonium acetate to separate the fragments (e.g. PCR products) via high performance liquid chromatography (HPLC) (Column 56, lines 3-33) and Ness et al apply PCR products to the carrier whereby the nucleic acids are bound to the carrier the separated fragments (Column 74, lines 26-59 and Column 75, line 62-Column 76, line 8). The teaching of Ness et al clearly suggests that the HPLC purified PCR are applied to the carrier. Following their suggestion, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply PCR products dissolved in betaine and HPLC purified to the carrier of Ness et al for the obvious benefits of binding PCR products of correct size to the carrier as suggested by Ness et al (Column 56, lines 31-33)

Regarding Claim 2, Ness et al teach the method for binding nucleic acids to a carrier wherein the nucleic acids are dissolved in a solvent containing at least one betaine, applying the nucleic acid solution to the carrier whereby the nucleic acids are bound to the carrier i.e. Ness et al dissolves nucleic acids in triethylammonium acetate to separate the fragments (e.g. PCR products) via high performance liquid chromatography (Column 56, lines 3-33) the

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separated fragments (e.g. PCR products) in the obtained solution are then applied to a carrier to bind the nucleic acids thereto)Column 74, lines 26-59 and Column 75,line 62-Column 76, line 8) wherein the betaine is triethylammonium acetate but not trimethylammonium.

However, based on their similar physical and chemical similarities and absent unexpected results, one of ordinary skill in the art would have expected the triethylammonium acetate to function in a similar manner as the trimethylammonium. Therefore one of ordinary skill in the art would have substituted the instantly claimed trimethylammonium acetate for the triethylammonium of Ness et al based on the expected similar functionality.

The courts have stated with regard to chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904).

Regarding Claim 3, Ness et al disclose the method wherein the betaine is present in the solvent at a concentration of 8 mM to 6.5 M (Column 56, lines 25-33).

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
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March 14, 2003